REMARKS

Claims 1, 3-8, 10-17 and 19-24 are pending in the application.

Claims 1, 3-8, 10-17 and 19-24 have been rejected under 35 USC §112, first paragraph as allegedly not enabled. Applicant respectfully traverses this rejection.

The present claims recite the concurrent or sequential administration of α-interferon with thymosin or thymosin fragment. They also recite using an "anti-hepatitis C viral effective amount of α-interferon." The issue is whether the specification provides enough description of how to use the invention without undue experimentation.

Applicants submit that they had possession of the invention at the time of filing. Further, the specification does provide information to enable one of ordinary skill in the art at the time of the invention to practice the invention. The specification indicates that the interferon and thymosin are administered together or sequentially. The thymosin is administered ***twice weekly*** *(e.g. Monday and Thursday)* ***subcutaneous*** *injection of about* ***1500 to about 1700 μg*** *of TH-α1. The interferon is administered at a dose of about 900 to about 1200 μg/m^2 body surface area. The interferon is administered five times per week.*

Support for combination therapy:

On page 16, first paragraph, it states,

"*In this combination therapy regimen, one or more interferons (for example, recombinant interferon α-2b, Intron-A, Schering-Plough, Kenilworth, New Jersey) is (are) administered subcutaneously to subjects, e.g., human patients, at doses ranging between about 1MU and 3MU* ***along with or sequentially with*** *one or more thymosins, preferably including THNα1, at a dose of about 900 to about 1200 μg/m^2 body surface area.*"

THNα1:

On page 14, first paragraph, with regard to administering THNα1, it states,

"*For a typical human patient, an administration regimen of* ***twice weekly*** *(e.g. Monday and Thursday)* ***subcutaneous*** *injection of about* ***1500 to about 1700 μg*** *of TH-α1 or fragments therefrom is convenient. Dosages and length of treatment can be flexible, and can be determined by the subjects's clinical response to the thymosins.*"

It also states on page 13, second paragraph, that thymosin is administered in an amount of about 900 to about 1200μg/m2 body surface area and that this amount is "immune system potentiating."

INTERFERON:

The specification indicates the dosage and administration schedule as follows:

"Interferon is administered at a dose of about 900 to about 1200 μg/m^2 body surface area." Page16, first paragraph.

"Typically, injections are made five times per week and continue until an acceptable response by the subject is realized." Page 16, second paragraph.

The specification indicates that tests can then be made to monitor the effectiveness of the combination therapy for a particular patient.

The Examiner has asserted that the research at the time indicated that treatment efficacy for a different disease, Hep B, depended on a particular type of administration and asserted that one of ordinary skill in the art could not have predicted based on Hep B knowledge, how to administer Hep C treatment. Applicants have indicated in a previous response that Hep C is different than Hep B and therefore, agree with the Examiner that Hep B does not have a high degree of relevance. Because of their differences, the Hep B treatment, Hep B virus and journal articles relating to Hep B do not have any bearing on the enablement of this application.

There is no support for the statement that the lack of predicatability for Hep B is not overcome by the present specification for treatment of Hep C. As shown above by page and paragraph number, the present specification provides a treatment regimen complete with timing and dosage.

It is submitted that the specification is in compliance with §112, first paragraph.

Claims 1, 3-8, 10-17 and 19-24 have been rejected under 35 USC§112, first paragraph for because the Examiner asserts that the inventor may not have had possession of the invention at the time of filing. Applicant respectfully traverses this rejection.

The Examiner questions what thymosin fragments potentiate the immune system. The specification indicates that the thymosins preparations suitable for treating HCV infections include "*TF-5, THNα1 and fragments thereof, e.g. C-terminal 4-28 and 15-28,*

and N-terminal 1-8, 1-14 and 1-20 fragments. These may be obtained from Alpha-1 Biomedicals Inc., Foster City, California." Page 13, first paragraph. On page 12, last paragraph, it states that the thymosins or thymosin fragments can be *"naturally occurring in the thymus gland or produced by chemical or recombinant means."* It is respectfully submitted that the Applicant had possession of the invention at the time of filing.

Reconsideration and allowance are respectfully requested.

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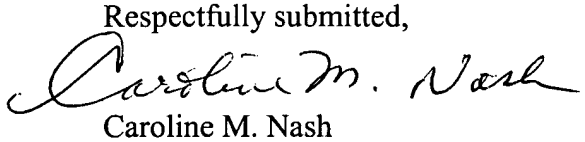
Respectfully submitted,



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